# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

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National Starch and Chemical Holding Corporation, Penford Australia Ltd., and Penford Holdings Pty.,	Investment	: : : : : : : : : : : : : : : : : : : :	
	Plaintiffs,	:	
v.  Cargill Corporation and MGP Ingredients, Inc.	Defendants.	: : : : :	Civil Action No. 1:04-cv-1443

# PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION FOR LEAVE TO FILE FIRST AMENDED ANSWERS AND COUNTERCLAIMS

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Plaintiffs, National Starch and Chemical Investment Holding Corporation ("National Starch"), Penford Australia Ltd. ("Penford Australia"), and Penford Holdings Pty. ("Penford Holdings" and collectively, with Penford Australia, referred to herein as "Penford") hereby oppose defendants' Motion for Leave to File First Amended Answers and Counterclaims. Defendants' motion should be denied since it is untimely, offers a futile amendment in any event, and is grossly prejudicial to plaintiffs National Starch and Penford.

#### NATURE AND STAGE OF PROCEEDINGS

On November 12, 2004, plaintiffs National Starch and Penford brought this patent infringement action against defendants Cargill and MGPI for infringement of U.S. Patent Nos. 5.977.454 ("the '454 patent") and 6.409.840 ("the '840 patent"). The '454 and '840 patents concern hybrid maize seeds and starch having greater than 80% amlyose content, thereby imparting desirable dietary and processing properties into products made from that starch. Cargill and MGPI are infringing the '454 and '840 patents by growing maize plants from seeds covered by the '454 patent and processing them into starch products covered by the '840 patent.

All parties to this case agreed on April 29, 2005 to a stipulated scheduling order, which set a deadline of September 30, 2005 for filing any motion to amend the pleadings. (See D.I. 25, 26.) That stipulated scheduling order was adopted and entered by the court on May 5, 2005. (See Order of the Court, dated May 5, 2005.)

On February 1, 2006, ten months after it agreed to a deadline of September 30<sup>th</sup> for amending pleadings and four months after that agreed-to deadline passed, defendants filed a motion to amend their respective answers and counterclaims to add inequitable conduct and unfair competition counterclaims. In their motion to amend, defendants allege that the

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<sup>&</sup>quot;D.I" refers to the Court's Docket Index Numbers.

documents on which their motion is purportedly based were produced in response to document requests served by defendants on September 12, 2005. (*See* D.I. 81 at 2.) That service date is ten months after this case was filed and less than three weeks before the September 30<sup>th</sup> deadline for amending pleadings. Thus, defendants inexplicably waited to serve their document requests until it was too late for them to receive documents from plaintiffs before having to decide whether they wanted to move to amend their pleadings in a timely fashion.

Fact discovery is scheduled to close on February 15, 2006, less than one week from today. Initial expert reports are due on March 1, 2006, less than three weeks from today, with reply expert reports due on March 20<sup>th</sup>.

#### SUMMARY OF ARGUMENT

A motion for leave to amend made under Fed. R. Civ. P. 15(a), as defendants' motion is styled, is properly denied when the proposed amendment is unduly delayed, futile, or prejudicial to the opposing party. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 272-73 (3d Cir. 2001). Moreover, because defendants' motion to amend is untimely under the Court's May 5, 2005 Scheduling Order, it should be judged by the heightened "good cause" standard of Rule 16(b), not the relatively more-liberal standard of Rule 15(a) touted by defendants. In either case, each of these three reasons (undue delay, futility and prejudice to plaintiffs) independently requires the denial of defendants' motion.

Defendants motion to amend their answers and counterclaims to add inequitable conduct and unfair competition claims comes a full four months after the scheduling order deadline of September 30, 2005 for moving to amend pleadings. Defendants have not shown any cause for this extraordinary delay, much less the good cause required by Rule 16(b). Indeed, defendants

acknowledge in their motion that they did not serve their document requests until September 12, 2005 (ten months after this case was filed), in response to which they could not have expected to even receive documents before the September 30<sup>th</sup> deadline for amending. Thus, defendants just ignored that deadline in terms of how they chose to manage their case.

In addition to being untimely, permitting amendment at this late hour would grossly prejudice National Starch and Penford. The addition of inequitable conduct and unfair competition claims would prejudice plaintiffs because it would substantially alter the focus of the case, forcing plaintiffs to engage in significant new preparations, discovery and depositions after the close of fact discovery on February 15<sup>th</sup>. Instead of focusing on expert reports and trial preparations, plaintiffs will be forced to deal with, for example, the subjective issues of intent underlying both the inequitable conduct and unfair competition claims. These issues have not yet been the subject of discovery. Further, to rebut defendants' unfair competition claim, plaintiffs will need to take additional discovery to establish how, if at all, defendants were harmed by any alleged "unfair competition." Via interrogatories, document requests, requests for admission, and depositions, plaintiffs will need to determine if this alleged "unfair competition" caused defendants to loose business, customers, sales, or otherwise suffer damage. Such discovery has also not yet occurred and cannot be completed by February 15<sup>th</sup>.

Moreover, not only will plaintiffs need to take additional discovery to defend against the proposed amended counterclaims, defendants will presumably require additional discovery as well. For example, defendants have recently (on February 3<sup>rd</sup> and 7<sup>th</sup>) served notices of two additional depositions (James Lallie and Jeff Lyndon) that cannot be completed by the close of discovery. Allowing these new counterclaims into the case would also require plaintiffs to obtain new experts and get them up to speed before the fast approaching expert report dates of

March 1<sup>st</sup> and 20<sup>th</sup> and engage in far more extensive and vast expert discovery regarding these counterclaims. In sum, forcing plaintiffs to engage in additional discovery, entirely different in content, substance, and character to that which has already occurred, at a time when it should be focusing on expert reports and trial strategy, would be grossly prejudicial.

Lastly, defendants' proposed inequitable conduct and unfair competition claims are also futile. Tellingly, defendants did not even bother to attach to their motion the supposedly "highly material" Laboratory Studies on which their new counterclaims purportedly are based. Nor are those Laboratory Studies identified by Bates number. As for the arguments defendants make about these unidentified Laboratory Studies, they are merely a repackaging of the same failed arguments about amylose testing methods that defendants made in connection with their Markman briefing.

According to defendants, these "Laboratory Studies" should have been given to the PTO since they show that the amylose testing method of the patents-in-suit are unreliable and produce "substantially inflated results." (See D.I. 81 at 3.) That argument makes no sense. The issue of different amylose tests giving different results was undeniably considered by the PTO throughout the prosecution of both patents-in-suit. Indeed, defendants unsuccessfully attempted to rely on such PTO considerations in arguing for a much broader claim construction that would have included any amylose test within the bounds of the claims, not just the test of columns 3 and 4 of these patents (as ultimately held by the Court). (See, e.g., D.I. 38 at 7-8).

#### **ARGUMENT**

## I. There Is No Good Cause For Defendants' Undue Delay In Moving To Amend

A court may deny a motion to amend based on undue delay when the movant is unable to satisfactorily explain the reasons for its delay. *See generally Foman*, 371 U.S. at 182; *Cureton*, 252 F.3d at 273; *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1413-14 (3d Cir. 1993). Here, defendants' filed their motion to amend a full <u>four months</u> after the deadline in the Court's scheduling order for amending pleadings. No satisfactory explanation was provided, much less good cause. Nor could it be, since defendants' new counterclaims rest on documents they did not attach to their motion, did not fully describe in that motion, and admittedly did not even seek from plaintiffs until it was too late to receive them before the September 30 deadline for moving to amend. Moreover, the same arguments that defendants now make to prop up their proposed counterclaims could have been made long ago, based on the public record in the PTO of the prosecution of the patents-in-suit (as defendants, indeed, did in their failed Markman briefing).

Not only did defendants not attach the Laboratory Studies to their motion, they did not even quote or describe any particular passages of these allegedly "highly material" studies. In fact, defendants have provided the Court with little more than their own assessment regarding the import of these materials. If these documents were truly "highly material," it would have made sense for defendants to attach them as exhibits (or at least quote the most relevant passages) so as to highlight their purported relevance. Defendants' failure to do so emphasizes the disingenuity of their request for leave to amend. Defendants actions amount to little more than an attempt to gain a tactical advantage over plaintiffs, not only by moving to amend their answers and counterclaims at such a late hour, but also by failing to specifically identify the allegedly "new" evidence underlying their request for leave to amend. That, alone, warrants denying defendants'

motion. See generally Allergen, Inc. v. Alcon Inc., Civ. Act. No. 04-968, Docket Index No. 158 (D. Del. Jan. 17, 2006).<sup>2</sup>

Moreover, defendants incorrectly argued that their motion should be evaluated under Fed. R. Civ. P. 15(a), under which leave to amend is more liberally granted. But when a party seeks leave to amend after the deadline set by the scheduling order, as here, the motion is governed by the heightened "good cause" standard of Rule 16(b), not Rule 15(a). See Slip Track Sys., Inc. v. Metal-Lite, Inc., 304 F.3d 1256, 1269-70 (Fed. Cir. 2002) (affirming district court's reliance on Rule 16(b) in denying motion to amend); E. Minerals & Chems. Co. v. Mahan, 225 F.3d 330, 340 (3d Cir. 2000) (same); Parker v. Columbia Pictures Indus., 204 F.3d 326, 340 (2d Cir. 2000) (collecting cases). As explained by one court:

If we considered only Rule 15(a) without regard to Rule 16(b), we would render scheduling orders meaningless and effectively would read Rule 16(b) and its good cause requirement out of the Federal Rules of Civil Procedure.

Sosa v. Airprint Sys., Inc., 133 F.3d 1417, 1419 (11th Cir. 1998). Because defendants' motion to amend comes a full four months after the deadline for amending pleadings, it must be evaluated under Rule 16(b).

A party's satisfaction of the good cause standard of Rule 16(b) requires it to show that it was unable to meet the deadline despite the exercise of diligence. *See Parker*, 204 F.3d at 340. For example, in *Eastern Minerals*, the plaintiff sought to amend its complaint to add claims, the viability of which it had only recently became aware. *See E. Minerals & Chems.*, 225 F.3d at 340. The district court denied the motion (like here, made many months after the scheduling order's deadline) because the plaintiff had not explained why it did not obtain the information

<sup>&</sup>lt;sup>2</sup> Copies of all unpublished opinions cited herein have been attached to the end of this memorandum for the Court's convenience.

earlier. The Third Circuit affirmed. Id. The district court decided the matter under Rule 16(b), but noted that the unexplained delay would also allow the court to deny the motion under Rule 15(a). See id. Likewise, here, defendants offered no explanation for their failure to serve the documents requests until ten months into this litigation, at which time they could not even have expected to receive documents before the September 30 deadline for amending.

Defendants attempt to excuse their delay by asserting that it was plaintiffs that "delayed in disclosing highly material documents," particularly the Laboratory Studies, which allegedly "reveal that the method set forth in the patents in suit was unreliable and produced substantially inflated results." (D.I. 81 at 1). To the extent the Laboratory Studies even make such revelations, which is not true, defendants have been in possession of publicly available materials containing similar "revelations" regarding colorimetric amylose testing and general iodine binding procedures for many months. Indeed, defendants cited and relied on such materials in their Markman briefs.

For example, Defendants attached M.J. Wolf et al., Amylose Determination in Dimethyl Sulfoxide Extracts of Maize, in 47 Cereal Chemistry 437, 439 n.3 (W. Bechtel et al eds., 1970) to their Opening Markman Brief (see D.I. 39, Ex. 12). This article states that: "The term 'amylose' as used here is equivalent to the term 'apparent amylose'...; the latter presupposes that a part of the iodine is sorbed by long side chains on the branched starch component. If this condition exists, amylose values of starches should be somewhat high...." Likewise, Virgil Fergason, High Amylose and Waxy Corns, in Specialty Corns 55, 58 (Arnel R. Hallauer ed., 1994), another article attached to Defendants' Opening Markman Brief (see D.I. 39, Ex. 5), states that: "Potentiometric iodine titrations and spectrophometeric analyses have been used extensively to determine amylose-amylopectin ratios of various starches.... A review of these methods by

Shannon and Garwood ... points out that the amylose estimated by these procedures should be considered 'apparent amylose' because the occurrence of branched chain components with long external chains can result in an overestimation of amylose."

As is apparent from these passages and citations, defendants have long been in possession of materials which use language and express opinions virtually identical to the supposed "new facts" on which their inequitable conduct and unfair competition claims are premised. That is not surprising since it was well known during the prosecution of the patents-in-suit that different amylose tests gave different results. The PTO considered those facts during the prosecution and, indeed, defendants tried to rely on such considerations during their failed Markman arguments. Thus, while there is no basis for defendants new counterclaims, even if there were such a basis defendants could have brought their counterclaims long ago (by September 26, 2005 at the very latest, the date on which Defendants' filed their Opening Markman Briefing). Defendants inexplicably failed to file their motion until the very end of fact discovery, referencing recently produced Laboratory Studies which contain statements which, at best, are merely cumulative of those contained in the many publicly available articles long in Defendants' possession. See Cureton, 252 F.3d at 273 (noting that "[d]elay may become undue when a movant has had previous opportunities to amend a complaint"); Lorenz, 1 F.3d at 1414 (denying plaintiff's motion for leave to amend and finding that plaintiff had unreasonably delayed after noting that

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Defendants also cited articles containing similar statements in their Answering Markman brief: see, e.g., Jack C. Shannon & Douglas L. Garwood, Genentics and Physiology of Starch Development, in Starch: Chemistry and Technology 25, 31 (Roy L. Whistler et al eds., 1984) (attached as an exhibit to Defendants' Answering Markman Brief (see D.I. 42, Ex. B)); and produced a number of additional publicly available articles addressing the efficacy of colorimetric amylose testing in response to Plaintiffs' document requests: see, e.g., W. Banks et al., Studies on Starches of High Amylose Content, in 26 Die Starke / Starch 289, 291 (1974) (produced by Cargill as C000451-522); W. Banks et al., The Characterization of Starch and Its Components, in 26 Die Starke / Starch 73, 77 (1974) (produced by Cargill as C000082-87).

"[m]ost of the facts" included in the amended complaint were "available to plaintiff ... before she filed her original complaint").

#### Defendants' Inequitable Conduct and Unfair Competition Counterclaims are Futile II. and Meritless

A separate ground for denying leave to amend is futility of the proposed amendment. See Foman, 371 U.S. at 182. An amendment is futile if it would not withstand a motion to dismiss. See Satellite Fin. Planning Corp. v. First Nat'l Bank, 646 F. Supp. 118, 120 (D. Del. 1986). Here, even assuming the truth of defendants' allegations, the alleged misconduct does not state an inequitable conduct claim. Since the unfair competition claim is entirely premised on the alleged inequitable conduct, it too is futile and must be denied.

The elements of inequitable conduct based on omitting information are: (1) the information is material; (2) the applicant knows of the information and of its materiality; and (3) the applicant fails to disclose this information with the intent to mislead the PTO. See Lifescan, Inc. v. Home Diagnostics, Inc., 103 F. Supp. 2d 379, 382-83 (D. Del. 2000). Defendants' allegations do not satisfy these elements, and indeed, its charge of inequitable conduct is precisely the type of indiscriminate claim that, as the Federal Circuit has lamented, has become a "plague" on the courts. See Magnivision, Inc. v. Bonneau Co., 115 F.3d 956, 960 (Fed. Cir. 1997).

The Laboratory Studies, which defendants state "reveal that the method set forth in the patents in suit was unreliable and produced substantially inflated results," would not have provided the patent examiner at the PTO with any information that he did not already have. For example, during the prosecution of the '840 patent, the examiner cited an article authored by F.R. Senti, entitled High-Amylose Corn Starch: Its Production, Properties, and Uses. See '840 patent's prosecution history, July 13, 1998 Office Action, p. 2 (previously provided to the Court as part of the Declaration of Andrew A. Lundgren. See D.I. 44, Ex. A 0085-88). This article states that: "the term 'apparent' is used or understood in reference to the amvlose content of high-amylose starches because the branched fraction in such starches, unlike that in ordinary starch, accounts for a substantial part of the iodine binding on which the analyses for amylose are based. Apparent amylose contents therefore are higher than true values. . . ." F.R. Senti, High-Amylose Corn Starch: Its Production, Properties, and Uses, in Starch Chemistry and Technology 499, 499 n.2 (R.L. Whistler et al. eds, 1967) (emphasis added) (attached as an Exhibit to Defendants' Opening Markman Brief. See D.I. 39, Ex. 9).

Thus, while the specific Laboratory Studies cited by Defendants may not have been given to the PTO during prosecution of the patents-in-suit, the examiner was cognizant of the fact that some were of the opinion that amylose percentage determination methods utilizing iodine binding, like the colorimetric method disclosed in the patents-in-suit, can produce higher than expected results. Accordingly, defendants' arguments about what these Laboratory Studies state are merely cumulative of the art already considered by the examiner (and, indeed, are cumulative of the state of the art as a whole before the PTO). They cannot be "material" and cannot support an inequitable conduct claim. See Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991) ("A reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct.").

For all of the same reasons, since defendants' unfair competition counterclaim is entirely premised on their meritless inequitable conduct claim, (see D.I. 81 at 5), it too is futile and without merit.

# III. Plaintiffs Will Be Substantially Prejudiced If Defendants' Motion For Leave To Amend Is Granted

An amendment is prejudicial if it substantially changes the theory on which the case has been proceeding, and is proposed late enough that the opponent would need to engage in significant new preparation. See Pope v. MCI Telecomms. Corp., 937 F.2d 258, 263 (5th Cir. 1991); Archer Daniels Midland Co. v. Aon Risk Servs., 187 F.R.D. 578, 583 n.2 (D. Minn. 1999); Furman Lumber, Inc. v. Mountbatten Surety Co., Civ. Act. No. 96-7906, 1997 U.S. Dist. LEXIS 10120, \*5 (E.D. Pa. July 9, 1997). Undue prejudice is an independent ground for denying a motion to amend. See Foman, 371 U.S. at 182; Archer Daniels Midland, 187 F.R.D. at 583 n.2.

Here, fact discovery closes on February 15, 2006, only six days away. For the entire discovery period, plaintiffs had no notice that inequitable conduct or unfair competition was at issue in this case. Until now, all parties have conducted discovery relating only to the original claims, which address objective issues of infringement and validity of the '454 and '840 patents. In contrast, the proposed amendments both interject subjective issues of intent. Further, an unfair competition claim would require inquiry into the alleged damage suffered by defendants. The addition of these intent and damage based counterclaims would unfairly force plaintiffs to alter their trial strategies and engage in significantly different trial preparation at this late date. See Cureton, 252 F.3d at 275-76; Samick Music Corp. v. Delaware Music Indus., Inc., Civ. Act. No. 91-23, 1992 U.S. Dist. LEXIS 2464, \*20-21 (D. Del. Feb. 12, 1992). Defendants' motion must be denied on that basis alone.

Indeed, "[i]t is well-settled that prejudice to the non-moving party is the touchstone for the denial of an amendment." *See Cornell & Co. v. Occupational Safety & Health Review Comm'n*, 573 F.2d 820, 823 (3rd Cir. 1978). Litigation defendants' new counterclaims will

require significant investigatory efforts and additional discovery which cannot reasonably be completed before the end of fact discovery on February 15th. Forcing plaintiffs to engage in such discovery, when their attention should be focused on expert discovery and trial preparations, will result in substantial and undue prejudice. See generally Cureton, 252 F.3d at 273 (noting that the 3rd Circuit "consider[s] whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or new theories" when determining whether the non-movant will be substantially prejudiced by a proposed amendment); Berger v. Edgewater Steel Co., 911 F.2d 911, 924 (3d Cir. 1990) (affirming district court's denial of motion for leave to amend where "allowing the amendment here would inject new issues into the case requiring extensive discovery"); Jones v. United States Postal Serv., Civ. Act. No. 89-399, 1991 U.S. Dist. LEXIS 15547, at \*11 (D. Del. Oct. 2, 1991) ("An 'eleventh hour amendment' ... has been found to create a delay that is undue and prejudicial to the nonmoving party when new discovery would be required.").

More specifically, if Defendants are permitted to add their inequitable conduct and unfair competition defenses and claims, Plaintiffs will be forced to shift their focus away from their own preparatory efforts and the discovery presently requested by defendants, and will have to begin collecting information relating to these baseless counterclaims. Such efforts will require numerous interviews of company executives, the collection and review of potentially large numbers of additional documents, drafting of additional interrogatory requests and responses, and arranging depositions of high-ranking corporate officials.

To rebut defendants' unfair competition claim, for example, plaintiffs will need to determine the factual and legal bases underlying defendants' assertions and establish exactly how, if at all, any alleged "unfair competition" caused defendants to loose customers, sales,

business, or otherwise suffer damages. These issues have not yet been the subject of discovery. Moreover, a number of Cargill witnesses, including at least Joseph Holtwick and Peter Nielsen will need to be re-deposed, and additional 30(b)(6) witnesses will be required.

Defendants will also presumably require additional discovery in support of their proposed claims. Already, defendants have noticed two additional depositions (of Mr. Lallie and Mr. Lyndon) that cannot be scheduled and completed prior to the deadline of February 15<sup>th</sup>. With these new counterclaims, no doubt more depositions will be requested by defendants that will extend even further beyond that deadline date.

All of the above additional fact discovery will push up against the expert report dates of March 1<sup>st</sup> (opening) and March 20<sup>th</sup> (replies). Plaintiffs will need to obtain additional experts to address these new counterclaims, as well, further compounding this case and stretching plaintiffs' ability to prepare the remainder of its case.

In sum, it will be neigh impossible for National Starch and Penford to locate, produce, and provide documents and testimony to rebut Defendants' assertions of inequitable conduct unfair competition while simultaneously engaging in additional discovery to ascertain the factual bases underlying defendants' new allegations and claims for damages before the rapidly approaching end of fact discovery, only a few days away. Because Defendants' request for leave to amend will require such extensive additional fact and expert discovery in an extremely compressed period of time, granting defendants' request will substantially prejudice plaintiffs. Therefore, defendants' motion should be denied. *See, e.g., Buelna v. City of Phila*, Civ. Act. No. 01-5114, 2002 U.S. Dist. LEXIS 6018, at \*3-4 (E.D. Pa. Apr. 5, 2002) (denying plaintiffs' motion to amend after noting that plaintiffs' failed to request leave to amend until "four and a half months of the discovery period [was] behind them and two days left" and that plaintiffs'

proposed claims would require "additional extensive discovery." This additional discovery, which would have to occur in an extremely compressed time period, "present[ed] prejudice to the defendant.").

#### **CONCLUSION**

For each of the foregoing reasons, plaintiffs respectfully submit that defendants' motion for leave to amend their answers and counterclaims should be denied.

Dated: February 9, 2006

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### **CERTIFICATE OF SERVICE**

I, John W. Shaw, Esquire hereby certify that on February 9, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that February 9, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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